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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,422	05/09/2001	Xianxhang Yu	035879-0122	2132

22428 7590 12/15/2004

FOLEY AND LARDNER
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WASHINGTON, DC 20007

EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,422

Applicant(s)

YU ET AL.

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 19 and 24 is/are allowed.
- 6) ☐ Claim(s) 1, 3-7, 9-12, 14-18 and 25 is/are rejected.
- 7) ☒ Claim(s) 2, 13 and 20-23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 3, 5, 7, 8, , 16, 18, 19 and 22 have been amended. Claims 24-26 have been added. Claims 1-26 are pending and under consideration.

2. Sections of the text from Title 35, US code not found in this action can be found in a previous Action.

3. Claims 3-7 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claims 3 and 6 further limit the scope of claim 2. Claims 3 and 6 specify that analogs and derivatives of the pore forming peptides. It is unclear how 14 and 15 further limit the scope of claim 13. Claim 2 is limited to a pore-forming cytolytic peptide. Claim 13 is limited to a method reliant on a pore-forming cytolytic peptide. Thus, claims drawn to analogs and derivatives are broader in scope than pore-forming cytolytic peptides and broaden rather than narrow the scope of the dependent claims. For purpose of examination, claims 3 and 6 will be read as dependent on claim 1, rather than claim 2, and claims 14 and 15 will be read as dependent on claim 10, rather than on claim 13.

4. The rejection of claims 1, 3, 4, 6, 9-12, 14, 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained of reasons of record. New claim 25 is also rejected for the same reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is noted that the claims are rejected because the specification lack a definition of an "analog" and "derivative" and it is further noted that claims drawn to analogs and derivatives will be interpreted as being dependent on claims 1 and 10, rather than on claims 2 and 13 because dependency on the latter results in a broadening of the scope of the claims rather than a narrowing. The instant claims are rejected to the extent that they read on analogs and derivatives of the pore-forming cytolytic peptides. The

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claims encompass a genus comprising derivatives of pore forming cytolytic peptides; a genus comprising analogs or the pore-forming cytolytic peptides, and method reliant upon the identity of the species within all three genres. Each genus is highly variant because it tolerates species which differ substantially in structure from the parent pore-forming cytolytic peptides. The specification provides no limitations which would allow one of skill in the art to determine if a given protein was indeed a member of the claimed genus, because the structural requirements for membership within the genus are not defined by the specification or set forth as a claim limitation. The specification does not provide examples of a representative number of species which fall within the bounds of each of the genres. Thus, the disclosure of amoebapore, melittin and magainin does not sufficiently describe the claimed genus, because the genus encompasses members which differ substantially in structure from the parent compounds. One of skill in the art would reasonably conclude that applicant was not in possession of the genres analogs and derivative or pore-forming cytolytic peptides or procytotoxins which are not qualified in terms of structure. It logically follows that method claims reliant upon the identity of a genus of products which are not adequately described, cannot be adequately described.

Applicant argues that the specification states that 'modifications and derivitization according to the instant invention include but are not limited to substitutions, additions or deletions that provide for functionally equivalent molecules'. This has been considered but not found persuasive. The teachings in the specification are for purpose of providing examples, not as a limiting definition.

Applicant argues that conservative amino acid substitutions are well known in the art and therefore structural changes can be made to a cytolytic peptide without destroying function. This has been considered but not found persuasive. The claims are rejected under 112, first paragraph for lacking adequate written description of the genus of molecules encompassed by "procytotoxin" and analogs and derivatives of pore-forming cytolytic peptides. Because the claim limitations do not place constraints on the structure of analogs and derivatives and procytotoxins, the genus is highly variant and not adequately described by pore-forming cytolytic peptides.

Amendment of the claims to delete "analogs and derivative" and to incorporate the limitation of pore-forming cytolytic peptide in place of a procytotoxin would overcome the instant rejections.

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5. The rejection of claims 1-3, 6-7, 9-14, 17, 18 and 20 under 35 USC 103(a) as being unpatentable over Pinto et al (The Prostate Journal, Feb 1999, Vol. 1, pp. 15-26, cited in a previous Office action) in view of Julian et al (US 5,717,064) is withdrawn in light of applicants arguments.
6. The rejection of claims 1-7, 9-18 and 20-23 under 35 U.S.C. 103(a) as being unpatentable over Pinto et al (The Prostate Journal, Feb 1999, Vol. 1, pp. 15-26, cited in a previous Office action) and Julian et al (US 5,717,064). as applied to claims 1-3, 6-7, 9-14, 17, 18 and 20 above, and further in view of Leippe et al (PNAS, 1994, Vol. 91, pp. 2602-2606, cited in a previous Office action) is withdrawn in light of applicants arguments.
7. Claims 2, 13 and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
8. All other objections and rejections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Karen A. Canella, Ph.D.

12/13/2004

Karen A. Canella
KAREN A. CANELLA PH.D.
PRIMARY EXAMINER